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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,690	12/08/2003	Nurulain Zaveri	8500-0269.20	3278

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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/731,690	Applicant(s) ZAVERI ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 30-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0604; 1004 6) ☐ Other: _____
- 12/09

DETAILED ACTION

1. Claims 1-47 are pending.
2. Claims 30-47 are withdrawn from consideration. These claims have not been canceled.
3. In the response filed September 22, 2005, Applicants have elected the invention of Group I without traverse. The compound SR 13916 is the preferred species.

The Traversal of the Restriction

Applicants elect Group I, Claims 1-29, without traverse. However, applicants respectfully wish to traverse the grouping of the claims, and submit that claims 30-47 are not properly divided into separate groups.

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or Otherwise include all the limitations of the allowable product claim will be rejoined.

Accordingly, to the extent that treatment methods and chemopreventive methods utilizing compounds of formula (I) may be withdrawn from further consideration as being non-elected due to the restriction requirement, it is understood that claims drawn to these aspects of the elected invention may be rejoined at the appropriate time.

It is the Examiner's position that:

- The claims 30-47 are drawn to separate groups, which are proper.
- The claims are drawn to independent and patentable distinct inventions.

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- Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained until an elected product claim is not found allowable.
- As such, the elected invention of Group I (compound and composition) is the examined subject matter.

The Traversal of the Election of Species

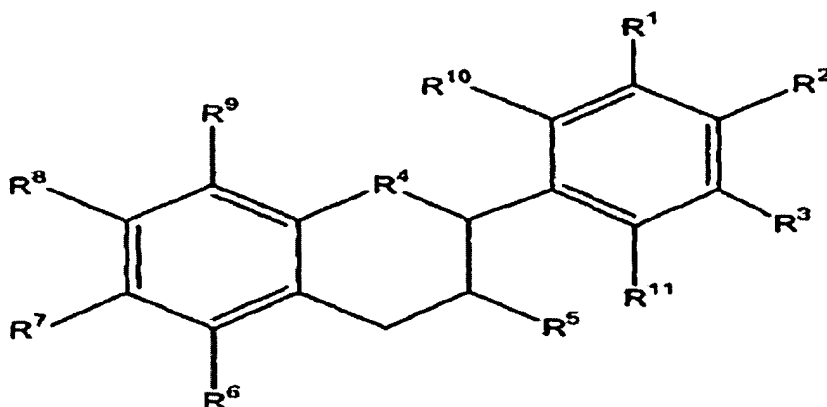
Applicants traverse the election of species requirement. R¹, R², R³, R⁴, R⁶, R⁷, R⁸, and R⁹ are not "species of the claimed invention", as stated by the Examiner, but rather represent classes of substituents that may be present on the compounds of the invention. Therefore, applicants submit that characterization of R¹, R², R³, R⁴, R⁶, R⁷, R⁸, and R⁹, as species is not proper, and respectfully request withdrawal of the election of species requirement.

It is the Examiner's position that:

- The compounds within the scope of claim 1 are drawn to patentably distinct species.
- While the characterization of R¹, R², R³, R⁴, R⁶, R⁷, R⁸, and R⁹ may be improper to applicants, these radicals form the many species, which are claimed.
- It is noted that R⁴ represent O, S, N and C. When R⁴ represents oxygen, a proper search is class 549. When R⁴ represents nitrogen, a proper search is class 546. This ring system would represent a quinoline

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compound.



- The ring systems derived from the definition of R⁴ are independent and patentable distinct. As such, these compounds would support separate patents.
- The search has been extended beyond the ultimate species of Example SR13916. See the examined subject matter below.
- The election of species requirement is maintained.

The Traversal of the Claim Groupings

Applicants state these methods of use are not properly subject to restriction, as they are not independent inventions (as required by 35 U.S.C. 121). The treatment of cancer and chemoprophylaxis of cancer are connected in that they are both methods directed toward avoiding the deleterious effects of the disease. Indeed, "preventative treatment" is a common medical term that refers to the application of measures desired to protect a person from attack of a disease. For at least the foregoing reasons, restriction of claims 30-47 into Groups II and III is improper and applicants respectfully request withdrawal of the grouping of the claims.

It is the examiner's position that:

- Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.
- Groups II and III are drawn to independent inventions. Group II is drawn to a method to treating cancer using the compound of formula (I). Group III is drawn to a method of preventing cancer using the compound of formula (I).
- If rejoined, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.
- Groups II and III do not meet the requirements of 35 U.S.C. 112, 1st paragraph.
- As such, the elected invention of Group I (compound and composition) is the examined subject matter.

The requirement is still deemed proper and is therefore made **FINAL**.

4. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

5. Claims 1-29 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

6. Claims 1-29 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are R¹-R⁹.

7. The examined subject matter is as follows:

A compound of formula I where R⁴ is O; R¹ and R² or R² and R³ do not form a cyclic ring; and R⁶ and R⁷ or R⁸ and R⁹ do not form a cyclic ring. Amending the claims to the examined subject matter would overcome the improper Markush rejection.

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8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5-7, 8, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claims 5-7, there is no antecedent basis for the phrases, "cis", "trans", and "racemic mixtures", at claim 1 on which it depends.

B. At claim 8, the phrase "such that the compound has the structure of formula (II)" is unclear. Where is formula (III)?

C. At claim 13, the phrase "R⁶, and R⁸" should be amended to read as --R⁶ and R⁸--.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1- 10, 14-16, and 18-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Li et al (Reference AD, cited by Applicants).

The instantly claimed compounds are disclosed. At page 740, 1st column, Figure 1, see compound 2b. At page 740, 2nd column, Scheme 2, see compounds 10b and

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12b. At page 741, 1st column, Scheme 3, see compounds 15b and 15c. These compounds are not excluded by proviso.

12. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Clark-Lewis (Reference AM, cited by Applicants).

The instantly claimed compound is disclosed. See RN 802-38-0.

13. Claims 1-4, 8-10, 14-16, 18-20, and 23-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Albert et al (Reference A).

The instantly claimed compounds are disclosed. At pages 1 and 2, see the generic formula (I).

14. Claims 1-10, 14-14, and 18-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bam et al (Reference U).

The instantly claimed compounds are disclosed. At page 284, see compounds 9 and 10.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/313,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because the radicals overlap. See R¹, R², and R³.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

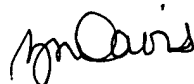
17. The Information Disclosure Statements filed June 7, 2004, October 14, 2004, and December 16, 2004 have been considered.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

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19. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Zinna Northington Davis
Primary Examiner
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